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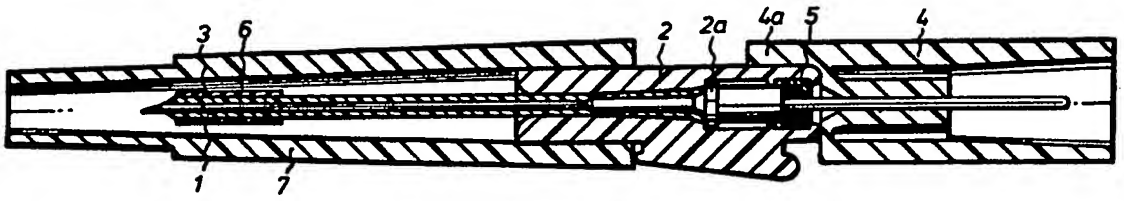

(57) Abstract

A catheter assembly includes a self-sealing membrane (5) mounted within a passageway of a housing (2). The membrane (5) is maintained within the passageway by forming the proximal end of the housing (2) on to the peripheral area of the membrane (5) thereby causing the centre of the membrane (5) to bulge such that a surface (5a) is made flush with said proximal end of the housing (2).

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IMPROVED CATHETER ASSEMBLY

The present invention relates to catheter assemblies and in particular to catheter assemblies for use by patients for the self administration of drugs such as insulin in the case of diabetics or other suitable medicaments.

Catheter assemblies are know which incorporate a sealing member to prevent or inhibit the ingress of foreign bodies or bacteria into the catheter assembly. United States Patent No. 4496348 discloses a catheter assembly comprising an elongate housing with a passageway extending longitudinally therethrough. A cannula tube is connected to the housing and extends outwardly from the distal end of the passageway. At its proximal end the passageway has mounted therein an elastic sealing member to prevent or inhibit the ingress of foreign bodies and bacteria into the interior of the catheter assembly. A puncture unit includes a needle having attached thereto a gripping head, the needle extends through the membrane, passageway and the cannula tube such that its spiculated end extends from the distal end of the cannula tube. The puncture unit is adapted for insertion and removal from the housing and the cannula tube. Means are provided for compressing the elastic sealing member to reseal the opening through said sealing member created by the withdrawal of the needle when the puncture unit is removed from the housing and the cannula tube.

This known catheter assembly suffers from the disadvantage that the needle puncturing surface of the membrane is relatively inaccessible and therefore cannot easily be cleaned. Furthermore, the compressing means necessary for resealing the sealing member is complicated which renders the catheter assembly relatively expensive to manufacture.

It is an aim of the present invention to provide a catheter assembly which is suitable for the self-administration of drugs or other medicaments by a patient in which the sealing member is self-sealing and is relatively easy to keep clean.

According to the present invention a catheter assembly comprises an elongate housing with a passageway extending longitudinally therethrough, a cannula tube connected to the housing and extending outwardly from the distal end of the passageway, the passageway at its proximal end having mounted therein a sealing member, and a puncture unit including a needle having attached thereto a gripping head, the needle extending through the membrane, passageway and the cannula tube with its spiculated end extending from the distal end of the cannula tube, the puncture unit being adapted for insertion and removal from the housing and the cannula tube, characterised in that the sealing member is a self sealing membrane which is mounted in the passageway and maintained therein at the proximal end of the housing by forming the proximal end of the housing on to the peripheral area of the membrane such that a surface of the membrane is made flush with the proximal end of the housing.

An embodiment of the invention will now be described, by way of example, with reference to the Figures of the accompanying diagrammatic drawings in which:-

Figure 1 is a cross section through a catheter assembly;

Figures 2A and 2B are cross sections illustrating schematically a method whereby a housing forming part of the cannula assembly of Figure 1 is formed over a membrane also forming part of the catheter assembly of Figure 1;

Figure 2C is a cross section of a hot forming tool for performing the operation illustrating in Figures 2A and 2B;

Figure 3 is a schematic cross section on an enlarged scale showing openings in a cannula tube forming part of the catheter assembly of Figure 1;

Figure 4 is a cross section illustrating a cannula tube forming part of the catheter assembly of Figure 1 assembled to a bushing;

Figure 5A is a cross section of a gripping head forming part of a puncture unit, said puncture unit forming part of the catheter assembly of Figure 1;

Figure 5B is an end view of the gripping member of Figure 5A;

Figures 6 to 8 are schematic views illustrating how the catheter assembly is handled prior to its use by a patient.

As shown, a catheter assembly includes an elongate housing (2) having an internal passageway extending from one end of the housing to the opposite end in the longitudinal sense. A cannula tube (1) made, for example of TEFLON, is connected to the housing (2) and extends from the distal end of the passageway. The cannula tube (1) is connected to the housing (2) by means of a bushing (2a) best illustrated in Figure 4, which bushing is located in an enlarged portion of the passageway. Also located in the enlarged portion of the passageway immediately adjacent to the proximal (right) end as shown in Figure 1 is a self-sealing silicon membrane (5).

Referring in particular to Figure 2a, 2b and 2c, the membrane (5) when inserted in the passageway is in the form of plug which engages the rear (right hand end as shown in Figure 2a) of the bushing (2a). In this way, there is only a minimum of dead space, that is, internal volume in the passageway of the housing (2). The membrane (5) is fixed in the passageway by the thermo-forming or ultrasonic-forming of the rear end or the housing (2). The Figures 2a, 2b and 2c illustrate the

case of thermo-forming. The rear end of the housing (2) is formed over the rear end of the membrane (5) by means of a forming tool and engages the peripheral area of the membrane with such a force that the membrane (5) is caused to bulge at its centre such that a needle-puncturing surface (5a) is made flush with the proximal end of the housing (2) which surface (5a) is readily accessible for cleaning.

The rear portion of the bushing (2a) has a conical bore. The largest cross section of the conical bore at its rear end being larger than the coaxial needle puncturing surface (5a) of the membrane (5) and serves as a guide means for a hypodermic needle passing through the membrane (5).

A portion of the tube (1) adjacent its distal end is coated with silicone (6).

Extending from each side of the housing (2) in a manner known per se are wings best illustrated in Figure 6.

The catheter assembly also includes a puncture unit which comprises a puncture member in the form of a hollow needle (3) and a gripping head (4) secured thereto. The needle extends through the membrane (5) passageway and cannula tube (1) such that its spiculated end extends from the distal end of the cannula tube (1).

As shown in Figure (5a), the gripping head (4) is formed at one end (right hand as shown) with a tapered bore and at its opposite end with an arcuate shaped flange (4a). The proximal or right hand end of the housing (2) in the assembled condition of the catheter assembly is located within the flange (4a) as shown in Figure 1. The flange (4a), in effect, encloses to a large extent the rear end of the housing (2) and thus protects the membrane (5) against contamination.

A protective tubular member (7) is a press fit over a portion of the housing (2) and thereby covers and protects the cannula tube (1) and needle (3). The tubular member (7) has a tapered outer surface which is reduced at its distal end as shown in Figure 1. The reduced portion of the tubular member (7) is so dimensioned that it can fit within the tapered bore of gripping head (4) as will be explained.

Referring in particular to Figure (3) the cannula tube (1) is provided in its wall with through openings or slots (8) which when the cannula tube (1) is placed in the body of a patient and medicament injected therethrough allows the spreading of the medicament.

The openings or slots (8) can also be used for sterilising the interior of the cannula tube. Such sterilisation is otherwise difficult to carry out since the membrane (5) effectively seals the cannula tube at its rear end and the engagement between cannula tube (1) and the needle (3) effectively seals the catheter tube (1) at its front or distal end.

In use, the catheter assembly is packed in a sterile manner with the protective tubular member (7) mounted on the housing (2) thereby protecting the cannula tube (1) and the needle (3) as shown in Figure 1. After the package has been opened and just before the assembly is used, the protective tubular member (7) is removed and inserted in the rear end of the gripping head (4) as shown in Figure 6 without any fingers touching the cannula tube (1). By pinching the gripping head (4) with the thumb and index finger the user then inserts the needle (3) and the cannula tube (1) into the skin. The puncture unit together with the protective tube member (7) is then separated from the

housing (2) by the user holding the housing (2) with one hand and withdrawing the needle (3) by means of the gripping head (4) and the tubular member (7) with the other hand. The housing (2) together with the cannula tube (1) inserted under the skin is thereafter fixed to the skin by an adhesive PUR-foam disc 9 having a recess (10) for the housing (2).

The medicament, for example insulin, can thereafter be injected into the body by means of a hypodermic needle run through the needle puncturing surface (5a) of the membrane (5) and guided by the bushing (2a). The medicament spreads throughout a large area due to the openings (8) in the cannula tube (1).

The embodiment of the invention described above has a number of advantageous features. For example, the membrane (5) is self-sealing and the needle puncturing surface (5a) is relatively easy to keep clean since it is flush with the proximal end of the housing (2). Further, the protective tubular member (7) provides the double function of protecting the cannula tube (1) and needle (3) as well as the users fingers before use and during use of effectively increasing the length of the gripping head (4). This second function is particularly important if the user is self-administering a drug and is in a weakened condition or unaccustomed to injecting himself.

The openings (8) in the cannula tube (1) also have a double function namely:-

a) Spreading the medicament within the body; and
b) permitting sterilization of the interior of the cannula tube (1)

Finally, the passageway in the housing (2) has very little dead space due to the location of the membrane (5) immediately adjacent the bushing 2a.

CLAIMS

1. A catheter assembly comprising an elongate housing (2) with a passageway extending longitudinally therethrough, a cannula tube (1) connected to the housing (2) and extending outwardly from the distal end of the passageway, the passageway at its proximal end having mounted therein a sealing member (5), and a puncture unit including a needle (3) having attached thereto a gripping head (4), the needle (3) extending through the membrane (5), passageway and the cannula tube (1) with its spiculated end extending from the distal end of the cannula tube (1), the puncture unit being adapted for insertion and removal from the housing (2) and the cannula tube (1), characterised in that the sealing member is a self-sealing membrane (5) which is mounted in the passageway and maintained therein at the proximal end of the housing (2) by forming the proximal end of the housing (2) on to the peripheral area of the membrane (5) such that a surface (5a) of the membrane is made flush with the proximal end of the housing (2).

2. A catheter assembly as claimed in claim 1, characterised in that the gripping head (4) has an arcuate flange (4a) which, when the puncture unit is inserted in the housing (2), substantially encloses the proximal end of the housing (2) thereby protecting the membrane (5) from contamination.

3. A catheter assembly as claimed in claim 1 or claim 2, characterised in that a tubular member (7) is provided which is a press fit over a portion of the housing (2) and thereby covers and protects the cannula tube (1) and the needle (3), a portion of the outer surface of the tubular member (7) being tapered and so dimensioned that it can fit within a tapered bore at the proximal end of the gripping head (4) to effectively increase the length of the gripping head (4).

4. A catheter assembly as claimed in claim 1, 2 or 3 characterised in that the cannula tube (1) has through openings (8) for spreading medicament within the body into which the cannula tube (1) is inserted.

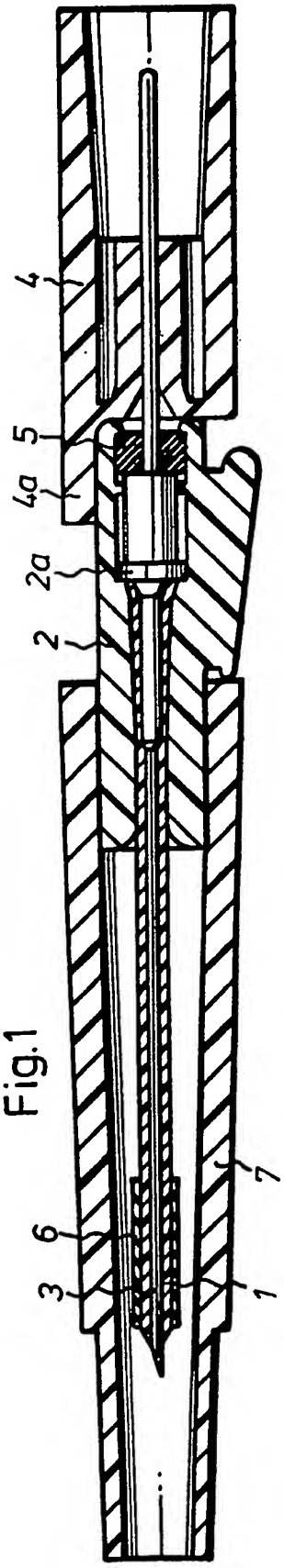


Fig.1

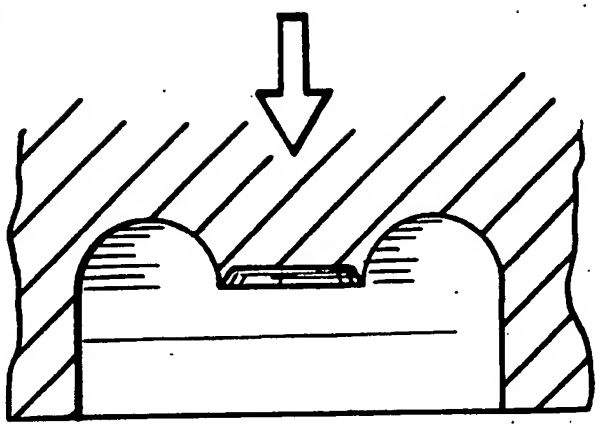


Fig.2c

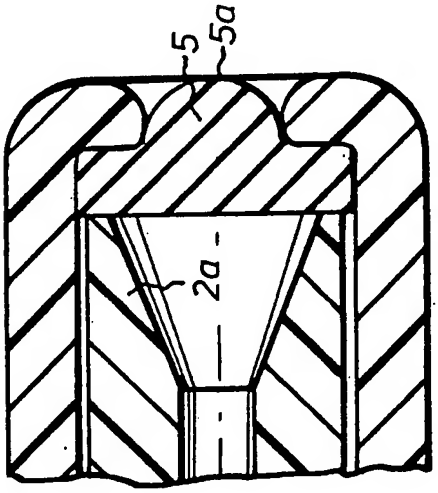


Fig.2b

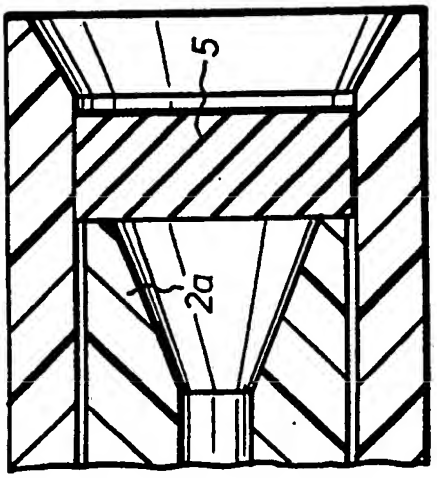


Fig.2a

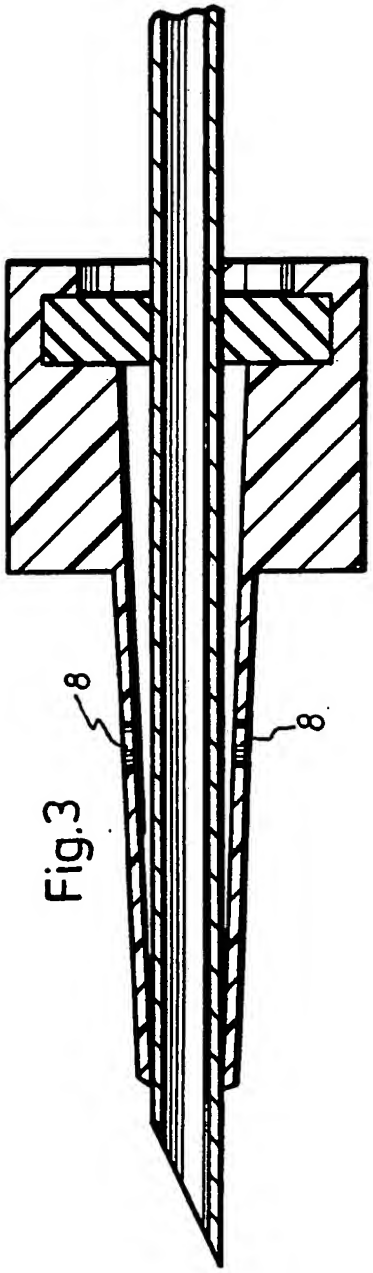


Fig.3

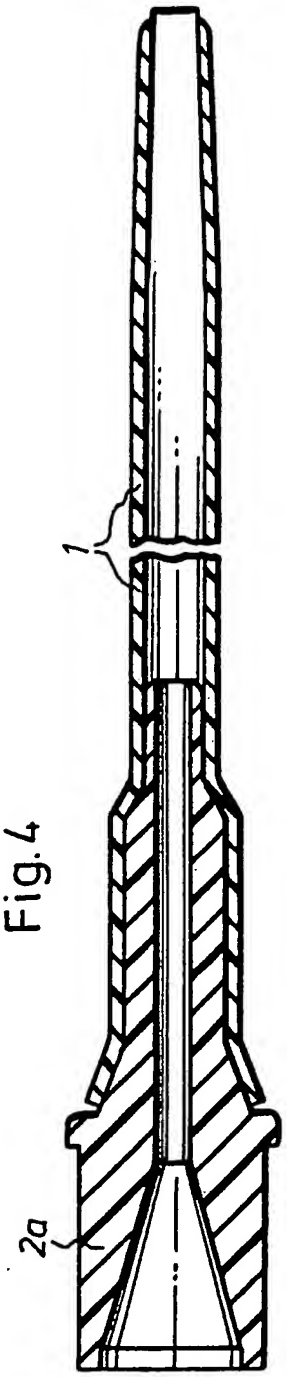


Fig.4

Fig.5a

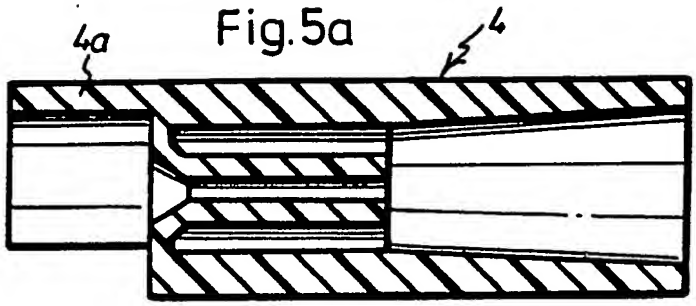


Fig.5b

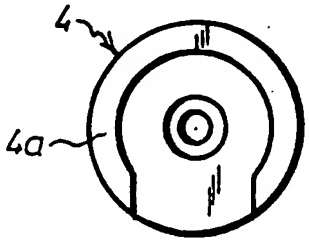


Fig.6

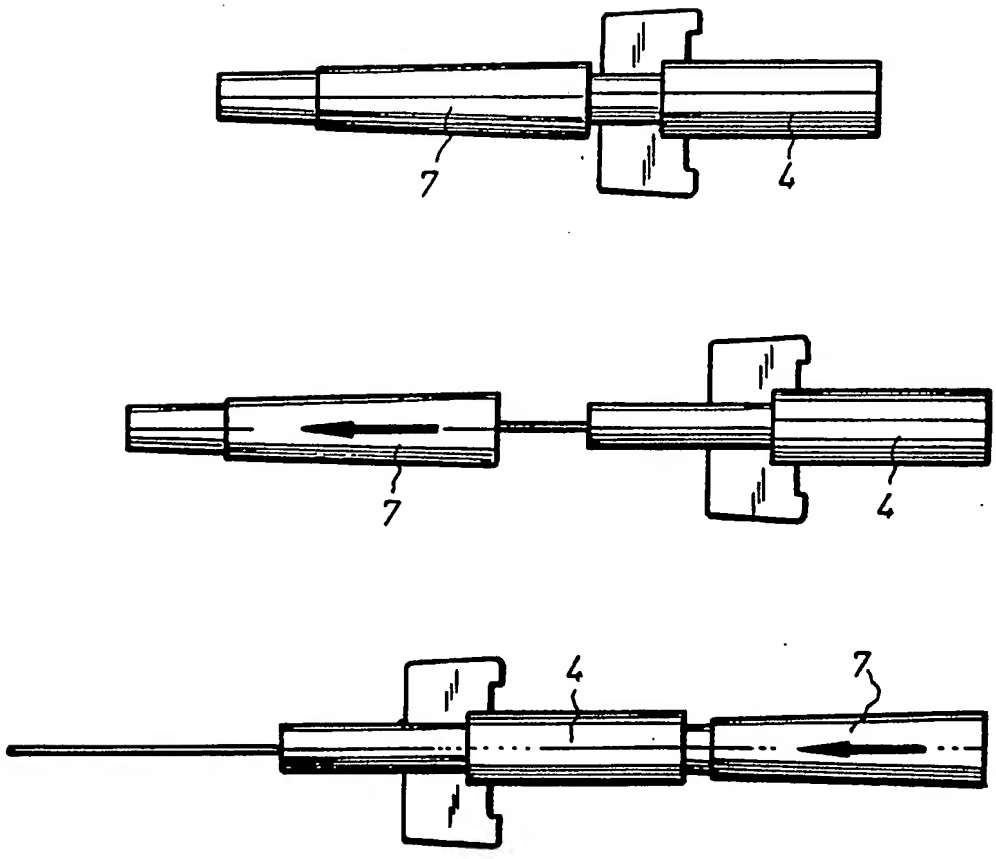


Fig.7

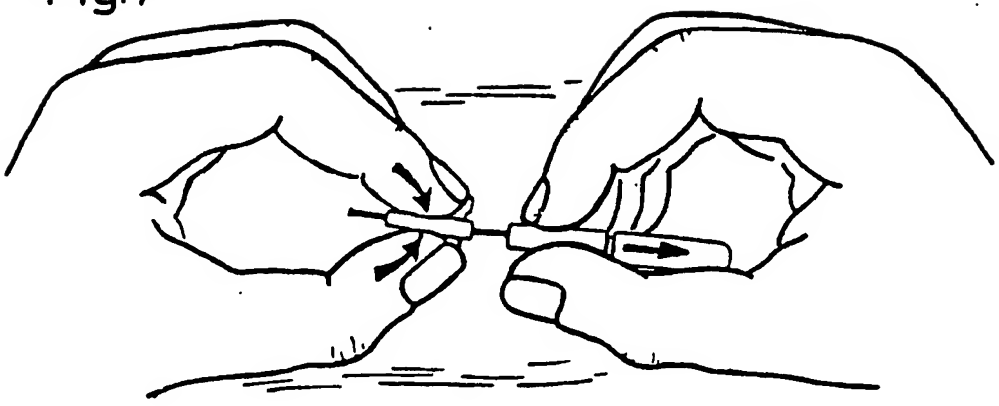
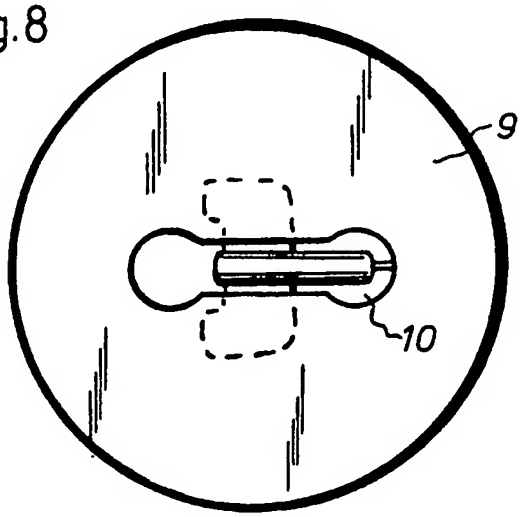


Fig.8



INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 87/00836

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[4]: A 61 M 5/14

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC[4]	A 61 M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
Y	GB, A, 2063679 (ABBOTT LABORATORIES) 10 June 1981 see the whole document cited in the application --	1,2
Y	US, A, 4294249 (SHEEHAN et al.) 13 October 1981 see figure 1; column 3, lines 5-37 --	1,2
A	US, A, 4601703 (HERLITZE) 22 July 1986 see figures --	1
A	FR, A, 1048549 (OGLE) 22 December 1953 see figures 1-5 --	3
A	US, A, 4601701 (MUELLER Jr) 22 July 1986 see figure 1 --	4
A	EP, A, 0137061 (CLARKE) 17 April 1985 see figures 10,11; page 6, lines 14-16 --	1

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
23rd February 1988	07 APR 1988
International Searching Authority: EUROPEAN PATENT OFFICE	Signature of Authorized Officer: P.C.G. VAN DER PUTTEN

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GB 8700836 SA 19573

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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
GB-A- 2063679	10-06-81	BE-A-	886409	16-03-81
		FR-A-	2470606	12-06-81
		DE-A-	3045005	03-09-81
		JP-A-	56125058	01-10-81
		AU-A-	6464280	04-06-81
		JP-A-	58192553	10-11-83
		US-A-	4496348	29-01-85
US-A- 4294249	13-10-81	None		
US-A- 4601703	22-07-86	None		
FR-A- 1048549		None		
US-A- 4601701	22-07-86	None		
EP-A- 0137061	17-04-85	US-A-	4447235	08-05-84
		WO-A-	8504795	07-11-85
US-A- 4511356	16-04-85	None		
EP-A- 0139091	02-05-85	JP-A-	60058164	04-04-85

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III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
A	US, A, 4511356 (FRONING et al.) 16 April 1985 see figures 1-4 --	1,2
A	EP, A, 0139091 (ABBOTT LABORATORIES) 2 May 1985 see figure 7 --------	4